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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Rea et al.

Serial No.: 09/666,430

Filed: September 21, 2000

For: DENDRITIC CELL ACTIVATED IN THE PRESENCE OF GLUCOCORTICOID HORMONES ARE CAPABLE OF SUPPRESSING ANTIGEN-SPECIFIC T CELL RESPONSES

Examiner: F. Vandervegt

Group Art Unit: 1644

Attorney Docket No.: 3157-4205.1US

CERTIFICATE OF MAILING

I hereby certify that this correspondence along with any attachments referred to or identified as being attached or enclosed is being deposited with the United States Postal Service as First Class Mail on the date of deposit shown below with sufficient postage and in an envelope addressed to the Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

April 28, 2008
Date

Betty Vowles
Signature

Betty Vowles
Name (Type/Print)

COMMUNICATION PROVIDING AMENDED STATUS OF CLAIMS AND SUMMARY OF CLAIMED SUBJECT MATTER IN AN APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

As indicated at MPEP § 1205.03, "[w]hen the Office holds the brief to be defective solely doe to appellant's failure to provide a summary of the claims subject matter as required . . ., an entire new brief need not, and should not be filed; rather a paper providing a summary of the clamed subject matter will suffice." Further, "[t]he Examiner should not require a corrected brief for minor non-compliance in an appeal brief." *Id.*

Pursuant to the above, applicants herein provide a Status of Claims section and a Summary of the Claimed Subject Matter section in compliance with 35 C.F.R. §§ 41.37(c)(1)(iii)

and 41.37(c)(1)(v), and request that these versions of the Status of Claims section and the Summary of the Claimed Subject Matter replace the sections of the same name in the Appeal Brief filed March 10, 2008.

Further, as this paper is submitted within one (1) month of mailing date of the Notice of Non-Compliant Appeal Brief (mailed March 28, 2008).

(3) STATUS OF THE CLAIMS

Claims 2 through 39 were cancelled without prejudice or disclaimer.

Claims 1, 40-49, 51-53, 55, 56, 58, 59, 61-63 and 65-68 stand rejected.

Claims 50, 54, 57, 60 and 67 are objected to.

Claims 64 and 69-81 are allowed.

The rejections of claims 1, 40-49, 51-53, 55, 56, 58, 59, 61-63 and 65-68 are being appealed.

(5) SUMMARY OF CLAIMED SUBJECT MATTER

The claimed invention provides means and methods for immunotherapy. The invention provides immune cells and methods to generate them, where the immune cells have the capacity, at least in part, to reduce an immune response in a host. *See*, Substitute Specification, mailed March 18, 2003, at page 6, lines 22-29. In one aspect, the invention provides a method for generating a dendritic cell with the capacity to tolerize a T-cell for the antigen the T-cell is specific for. *Id.*, at page 6 line 22 through page 7, line 12. More specifically, one aspect of the invention relates to culturing blood monocytes from a subject to differentiate into dendritic cells, activating the dendritic cells in the presence of a glucocorticoid hormone, and loading the activated dendritic cell with an antigen that a T-cell is specific for. *See*, Specification at *Id.*, at page 6 line 22 through page 7, line 24; page 8, lines 1-9; page 11, lines 6-24.

Independent claim 1 recites "a method for preparing a pharmaceutical composition for reducing an unwanted T-cell response in a host, said method comprising: culturing peripheral blood monocytes from said host to differentiate into dendritic cells; activating said dendritic cells with a means for reducing IL-12p40 production by said dendritic cells; loading said dendritic cells with an antigen against which said T-cell response is to be reduced; and forming a pharmaceutical composition comprising said loaded, activated dendritic cells for administration

to said host." Support for "a method for preparing a pharmaceutical composition for reducing unwanted T-cell response in a host" can be found at, for example, page 4, lines 23-25, and page 6, lines 22-34 of the Specification. Support for "culturing peripheral blood monocytes from said host to differentiate into dendritic cells" can be found at, for example, page 6, lines 35-36 of the Specification. Support for "activating said dendritic cells with a means for reducing IL-12p40 production by said dendritic cells," where dexamethasone is a structure identified as a means for providing said function, reducing IL-12p40 production by dendritic cells, can be found at, for example, Fig. 4 of the Drawings, and page 10, lines 25-26 of the Specification. Support for "loading said dendritic cells with an antigen against which said T-cell response is to be reduced" can be found at, for example, page 6, lines 37-38, and page 11, lines 19-23 of the Specification. And, support for "forming a pharmaceutical composition comprising said loaded, activated dendritic cells for administration to said host" can be found at, for example, page 6, line 41 through page 7, line 19 of the Specification. Support for these elements combined in the manner recited in claim 1 can be found at, for example, page 7, paragraph 19 of the Specification.

Independent claim 40 recites, "a method for preparing a pharmaceutical composition for reducing an unwanted T-cell response in a host against an antigen, said method comprising: culturing peripheral blood monocytes from said host to differentiate into dendritic cells; activating said dendritic cells with a glucocorticoid capable of activating a glucocorticoid receptor; bringing said dendritic cells into contact with an antigen against which said T-cell response is to be reduced; and forming a pharmaceutical composition comprising said loaded, activated dendritic cells." Support for "a method for preparing a pharmaceutical composition for reducing an unwanted T-cell response in a host against an antigen" can be found at, for example, page 7, lines 13-19 of the Specification. Support for "culturing peripheral blood monocytes from said host to differentiate into dendritic cells" can be found at, for example, page 6, lines 35-36 of the Specification. Support for "activating said dendritic cells with a glucocorticoid capable of activating a glucocorticoid receptor" can be found at, for example, page 9, lines 13-25 of the Specification. Support for "bringing said dendritic cells into contact with an antigen against which said T-cell response is to be reduced" can be found at, for example, page 11, paragraph [0035] of the Specification. And, "forming a pharmaceutical composition comprising said loaded, activated dendritic cells" can be found at, for example, page 6, line 41 through page 7, line 19 of the Specification. Support for these elements combined in the manner recited in claim

40 can be found at, for example, page 7, paragraph [0019] of the Specification.

Independent claim 51 recites, "a method for obtaining a dendritic cell capable of tolerizing a T-cell for an antigen, comprising: providing said dendritic cell with a substance capable of activating a glucocorticoid receptor; activating said dendritic cell; and providing said dendritic cell with said antigen; wherein said dendritic cell is capable of tolerizing a T-cell for said antigen." Support for "a method of obtaining a dendritic cell capable of tolerizing a T-cell for an antigen" can be found at, for example, page 8, lines 1-9 of the Specification. Support for "providing said dendritic cell with a substance capable of activating a glucocorticoid receptor" can be found at, for example, page 9, lines 13-25 of the Specification. Support for "activating said dendritic cell" can be found at, for example, page 11, paragraph [0035] of the Specification. And, support for "providing said dendritic cell with said antigen; wherein said dendritic cell is capable of tolerizing a T-cell for an antigen" can also be found at, for example, page 11, paragraph [0035] of the Specification. Support for these elements combined in the manner recited in claim 51 can be found at, for example, page 8, paragraph [0022] of the Specification.

Independent claim 56 recites, "a method for preparing an isolated dendritic cell, said method comprising: isolating peripheral blood monocytes from a subject; culturing the peripheral blood monocytes to differentiate into dendritic cells; activating the dendritic cells with a glucocorticoid; loading the dendritic cells with an antigen; and isolating said loaded, activated dendritic cells." Support for "a method for preparing an isolated dendritic cell" can be found at, for example, page 8, lines 20-23 of the Specification. Support for "isolating peripheral blood monocytes from a subject" can be found at, for example, page 11, line 26 through page 12, line 4 of the Specification. Support for "culturing the peripheral blood monocytes to differentiate into dendritic cells" can be found at, for example, page 6, lines 35-36 of the Specification. Support for "activating the dendritic cells with a glucocorticoid" can be found at, for example, page 8, lines 10-12. Support for "loading the dendritic cells with an antigen" can be found at, for example, page 6, lines 37-38, and page 11, lines 19-23 of the Specification. And, support for "isolating said loaded, activated dendritic cells" can be found at, for example, page 8, lines 20-21 of the Specification. Support for these elements combined in the manner recited in claim 51 can be found at, for example, page 6, line 23 through page 7, line 2 of the Specification.

Independent claim 65 recites, "a method for preparing a dendritic cell for tolerizing a T-cell in a graft or transplant recipient, said method comprising: culturing peripheral blood

monocytes from said graft or transplant recipient to differentiate into dendritic cells; activating said dendritic cells; and loading said dendritic cells with an antigen against which said T-cell is to be tolerized." Support for "a method for preparing a dendritic cell for tolerizing a T-cell in a graft or transplant recipient" can be found at, for example, page 6, line 23 through page 7, line 7 of the Specification. Support for "culturing peripheral blood monocytes from said graft or transplant recipient to differentiate into dendritic cells" can be found at, for example, page 6, lines 35-36 of the Specification. Support for "activating said dendritic cells" can be found at, for example, page 7, lines 22-24 of the Specification. And, support for "loading said dendritic cells with an antigen against which said T-cell is to be tolerized" can be found at, for example, page 6, lines 37-38, and page 11, lines 19-23 of the Specification. Support for these elements combined in the manner recited in claim 65 can be found at, for example, page 8, paragraph [0024].

As set forth in 37 C.F.R. 41.73 (c) (1) (vii), every means-plus-function claim must be identified and the structure materials or acts described in the specification corresponding to each claimed function must be set for the with reference to the specification. The current application contains a single means-plus-function claim, to wit: claim 1. The relevant means-plus-function language of claim 1 recites "activating said dendritic cells with a means for reducing IL-12p40 production by said dendritic cells."

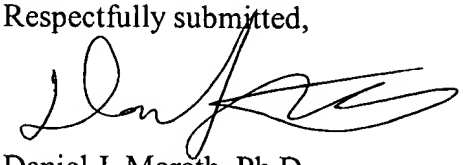
The specification, in Example 3 (*See*, Substitute Specification, mailed March 18, 2003, at page 10, line 19 through page 11, line 2.), clearly indicates that dexamethasone, a known compound, has the ability to reduce reducing IL-12p40 production by a dendritic cell, and is thus a disclosed means to accomplish this function. Further, the Patent Office, in the Office Action mailed July 26, 2005, at Page 5, agrees dexamethasone is a disclosed means for the function of reducing IL-12p40 production by said dendritic cells.

CONCLUSION

Applicants respectfully submit that the above provided status of claims and summary of the claimed subject matter comply with 35 C.F.R. § 41.37(c)(1)(v), and request that these versions of the status of claims and summary of the claimed subject matter replace the sections of the same name in the Appeal Brief filed March 10, 2008. If any questions remain after consideration of the foregoing, or the Office should determine that there are any additional issues which might be resolved by a telephone conference, the Office is kindly requested to contact the

applicant's undersigned attorney at the address or phone number provided herein.

Respectfully submitted,



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